UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE ASACOL ANTITRUST LITIGATION This Document Relates To: All End-Payor Actions	Civil Action No. 1:15-cv-12730 (DJC) PUBLIC REDACTED VERSION

DEFENDANTS' OPPOSITION TO END-PAYOR PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF DR. BRUCE A. STROMBOM

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INTRODUCTION

Plaintiffs' Motion provides no basis for excluding any—let alone the entirety—of the testimony of Dr. Bruce Strombom, Defendant's class certification and damage expert. Plaintiffs do not challenge Dr. Strombom's qualifications or the sufficiency and relevance of the data he used. Nor do Plaintiffs challenge the substance of Dr. Strombom's economic theories, or the actual calculations supporting his expert opinions. Instead, Plaintiffs narrowly argue that Dr. Strombom, an *economist*, applied an incorrect *legal* interpretation of "antitrust injury." According to Plaintiffs, this renders legally irrelevant certain aspects of Dr. Strombom's opinions, specifically, his opinions on the lack of antitrust impact, Plaintiffs' incorrect inclusion of uninjured parties in the proposed class, and how Plaintiffs' passing on of alleged overcharges under the laws of various states undercuts their class and alleged damages.

Plaintiffs' challenge to Dr. Strombom is wrong on both the facts and the law. ***First***, Plaintiffs seek to exclude all of Dr. Strombom's opinions,[1] but Plaintiffs' Motion challenges only certain narrow aspects of his opinions. For example, the Motion does not challenge the substantial flaws Dr. Strombom identified in the assumptions and impact analysis of Plaintiffs' expert, Dr. Conti (who, for example, assumed but did not test for impact). Nor does the Motion (other than an incorrect analysis of state pass-on law) challenge Dr. Strombom's overall damages opinions. ***Second***, Dr. Strombom's estimation of uninjured class members is based on unchallenged economics and does not require any prohibited "netting" of transactions, as Plaintiffs claim. In those instances where Dr. Strombom does provide averages for third-party payors ("TPPs"), he presents an estimation of uninjured class members, as specifically invited by the First Circuit in *In re Nexium Antitrust Litig.*, 777 F.3d 9 (1st Cir. 2015). ***Third***, Dr.

[1] End-Payor Plaintiffs' Mem. in Support of Mot.to Exclude the Testimony of Dr. Bruce A. Strombom ("Pl. Br.") at 3, ECF No. 447.

Strombom's showing that TPPs pass on any alleged overcharges through premiums is consistent with the many relevant state laws which allow a pass-on defense. And Plaintiffs themselves have conceded certain of the states allow pass-on defenses. ***Last***, Dr. Strombom's opinions regarding the lack of ascertainability of the proposed class are likewise consistent with governing precedent. And the ascertainability issues are critical, because Dr. Conti totally failed to present objective criteria for ascertaining class membership or an administratively feasible mechanism for distinguishing injured from uninjured class members. Plaintiffs' Motion to exclude any of Dr. Strombom's opinions must be denied.

BACKGROUND

Defendants' expert economist on class certification and damages, Dr. Bruce Strombom, is a Ph.D. economist with extensive damages and class-certification testifying experience.[2] Dr. Strombom provides an economic assessment of the reports on class certification and damages from expert Dr. Rena Conti, Plaintiffs' proposed expert. Dr. Strombom evaluated Plaintiffs' claims as to the (i) proof of class-wide impact using common evidence, (ii) class-wide damages methodology, (iii) estimated claimed damages, and (iv) ascertainability. Strombom Rep. ¶ 7.

Dr. Strombom identified substantial flaws in Dr. Conti's work and the proposed class. Regarding antitrust impact, Dr. Conti simply assumed common impact; she conducted no impact analysis. *Id*. ¶¶ 11, 34, 57. Dr. Conti's use of aggregated, nationwide prescription data—not consumer or TPP payment data—and national averages masked key variations in prices. *Id*. ¶¶ 11, 34-35, 57. Her model additionally ignored critical variations in health-plan-payment allocations and rebate agreements. *Id*. ¶¶ 12-13, 58-66. Dr. Conti also failed to follow the proposed class definition, failed to provide objective criteria for establishing class membership,

[2] *See* Expert Report of Bruce A. Strombom at Appendix A, attached as Exhibit A to Pl. Br. ("Strombom Rep.").

and failed to provide an administratively feasible mechanism for distinguishing injured from uninjured class members. *See, e.g.*, *id*. ¶¶ 14, 93-96.

Further, Dr. Strombom demonstrated that substantial numbers of uninjured class members may be included in the proposed class. These uninjured class members include brand loyal consumers, consumers who paid $0 for their brand purchases, consumers who would have saved no money on the generic, consumers who used coupons, TPPs who would have paid less for the brand as a result of copay/coinsurance differences and/or rebates, and TPPs who passed through any alleged overcharge via premiums. *Id*. ¶¶ 9-10, 36-55, 59-66, 96.[3]

Dr. Strombom showed that the numerous flaws in Dr. Conti's report, such as her failure to address the FDA's safety concerns regarding DBP and changes to the Delzicol product, rendered her framework for assessing damages useless as well. *Id.* ¶¶ 15-18, 81-84. As a result of these flaws, Dr. Conti significantly overstated damages in the four hypothetical generic entry scenarios she evaluated. *Id*. ¶ 18. Because of these deficiencies, Defendants moved to exclude Dr. Conti's opinions. *See* Defs.' Mem. in Support of Mot. to Exclude Certain Opinions and Testimony of Rena Conti at 1 ("Defs.' Mot. to Exclude Conti"), ECF No. 433.

ARGUMENT

I. PLAINTIFFS DO NOT CHALLENGE THE MAJORITY OF DR. STROMBOM'S OPINIONS—THEIR MOTION TO EXCLUDE ALL TESTIMONY IS UNFOUNDED

Plaintiffs' Motion does not challenge the majority of Dr. Strombom's opinions. There is

[3] Plaintiffs claim that Dr. Strombom equates impact and damages in his analysis. Pl. Br. at 5-6 (citing Strombom deposition testimony, attached as Exhibit B to Pl. Br. ("Strombom Dep.")). But Plaintiffs ignore Dr. Strombom's unequivocal testimony that impact and damages can be different. Strombom Dep. 280:15-281:2 ("Q. I want to know, I want you to testify under oath whether or not you use 'impact' and 'damages' synonymously, as you testified to? A. My answer was with respect to the question that was asked of me. 'Impact' and -- and 'damages,' I mean, can be different. The . . . effect or the impact and the measurement and quantification of damages can be -- can be different things." (objection omitted)).

no challenge or reference to Section VI.A-D of his Report, which (i) explains why Dr. Conti's overcharge framework and methodology do not demonstrate that injury can be determined using common evidence, and (ii) highlights the unrealistic assumptions by Dr. Conti and facts that she ignored. Strombom Rep. ¶¶ 75-95. Similarly, Plaintiffs do not challenge or even reference Section VII, which contains Dr. Strombom's damages opinions. *Id.* ¶¶ 99-114.

As to those limited parts of the Report Plaintiffs do reference, Plaintiffs fail to seriously challenge Dr. Strombom's economics, data, or analyses. Instead, Plaintiffs assert that a subset of Dr. Strombom's opinions are not relevant because he applied incorrect law. Pl. Br. at 2. But Dr. Strombom does not offer any legal opinions; rather, he provides economic opinions that are consistent with First Circuit law, and are relevant, helpful, and admissible as set forth below.

II. DR. STROMBOM'S OPINIONS REGARDING PLAINTIFFS' FAILURE TO SHOW CLASS-WIDE IMPACT WITH COMMON EVIDENCE ARE RELEVANT, RELIABLE, AND HELPFUL

Dr. Strombom determined that class-wide evidence does not exist to show antitrust impact for Plaintiffs' proposed class. Strombom Rep. ¶¶ 9-14. Instead, an individualized inquiry would be required. *Id.* ¶¶ 9; 33-74; *see, e.g.*, *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 20 (1st Cir. 2008) (common issues do not predominate where "fact of antitrust impact cannot be established through common proof"). Dr. Strombom identified multiple categories of consumers and TPPs with certain characteristics who were included in the proposed class but were uninjured. Strombom Rep. Sections V.A & C. Dr. Strombom explained why each group was uninjured, and he also used one of Dr. Conti's hypothetical, counsel-generated generic entry scenarios to show that the number of uninjured class members was more than de minimis. *E.g.*, *id.* ¶ 10, Table 1. In addition, Dr. Strombom's analyses made clear that Dr. Conti simply assumed class-wide impact where she: (1) relied on general economic studies about entry of AB-rated generic drugs unrelated to any facts in this case, including how the

FDA's safety concerns regarding DBP "could impact generic entry decisions and patient switching behavior"; and (2) used highly aggregated, national prescription data for a damages assessment, but that analysis does not show impact—it hides individualized variation, ignores the implications of factual allegations in the case, and ignores Named Plaintiffs' own transactional data. *Id.* ¶¶ 34, 45, 56-57.

Dr. Strombom's opinions more than satisfy the admissibility requirements of Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Dr. Strombom is qualified to offer the opinions in his report, and Plaintiffs do not argue otherwise. Dr. Strombom's opinions are relevant and helpful because they address impact and damages issues that are pertinent to the Court's class certification analysis and elements of the parties' claims and defenses. Fed. R. Evid. 702; *see also Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) ("expert testimony must be relevant not only in the sense that all evidence must be relevant, but also in the incremental sense that the expert's proposed opinion, if admitted, likely would assist the trier of fact to understand or determine a fact in issue" (citations omitted)).

Dr. Strombom's opinions are reliable because they are based on accepted economic principles and methods and sufficiently supported by relevant facts and data. Fed. R. Evid. 702; *see also Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11, 26 (1st Cir. 2011) (reversing exclusion of expert testimony where "record clearly demonstrates that Dr. Smith's opinion was based on an analysis in which he employed the 'same level of intellectual rigor' that he employs in his academic work.") (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). *Ruiz-Troche*, 161 F.3d at 81 (considering factors such as "the verifiability of the expert's theory or technique, the error rate inherent therein, whether the theory or technique has been published

and/or subjected to peer review, and its level of acceptance within the scientific community").

Plaintiffs' Motion presents a limited relevancy argument as to antitrust injury. Plaintiffs narrowly challenge Dr. Strombom's analysis of uninjured class members in some—but not all—consumer and TPP categories, claiming that he only evaluated "net" purchasing experiences, which makes these results "legally irrelevant." Pl. Br. at 4-5, 8. Plaintiffs misstate Dr. Strombom's analysis, and they are wrong on the law. Dr. Strombom's determinations regarding uninjured class members are consistent with prevailing law and thus admissible.

A. Dr. Strombom's Showing That Plaintiffs Failed To Exclude Thousands Of Uninjured Consumers From The Proposed Class Is Admissible And Useful

Underscoring the flaws in Plaintiffs' proposed class, Dr. Strombom estimates the number of uninjured consumers included in Plaintiffs' proposed class, focusing on four categories of uninjured consumer class members. Plaintiffs argue that some (but not all) of Dr. Strombom's estimates of uninjured consumer class members require a prohibited "netting" of transactions.[4] Plaintiffs are wrong.

Plaintiffs do not challenge Dr. Strombom's opinion as to 20% of proposed consumer class members that are uninjured. As an initial matter, Plaintiffs' "netting" argument does not challenge Dr. Strombom's estimation that about 20% of proposed consumer class members are uninjured consumers who fall into two important categories: (i) brand-loyal consumers; and (ii) consumers who likely would have switched to the alleged generic but with no cost savings. Strombom Rep. ¶¶ 36-39; 46-50. Dr. Strombom estimates that about 15% of consumer class members would be brand loyal, would not switch to a generic in the but-for world, and thus would not be injured. Strombom Rep. ¶¶ 36-39; *see Nexium*, 777 F.3d at 30 (confirming brand

[4] Plaintiffs concede that, even if there is antitrust impact, a class member may suffer no damages, and that offsets and recoupments are relevant to damages. Pl. Br. at 2; *see also Nexium*, 777 F.3d at 27.

loyal consumers "likely not injured"). Dr. Strombom also calculates that about [redacted] of consumer class members would experience no cost savings from a switch to a generic in the but-for world, and thus would be uninjured. Strombom Rep. ¶¶ 46-50; *see Nexium*, 777 F.3d at 26 (class member must be "overcharged" to suffer antitrust injury). Plaintiffs' Motion does not dispute the admissibility of these opinions, which highlight flaws in their proposed class definition and methodology.

Consumers who paid $0 are not injured. Plaintiffs misstate Dr. Strombom's analysis of consumers who paid $0, claiming that it requires a "netting" of separate prescription transactions. It does not. Dr. Strombom estimates that [redacted] of potential class members paid $0 for their actual world Delzicol or Asacol HD prescriptions. Strombom Rep. ¶¶ 9, 40-45. This includes consumers who made no payment for the drug. *Id.* ¶ 43. It also includes consumers who made a co-payment at the pharmacy counter, but who later were repaid the co-payment in accordance with the terms of their health plans. *Id.* ¶¶ 40-41. Plaintiffs do not challenge Dr. Strombom's ***economic*** analysis of "no injury" in either situation. Instead, Plaintiffs characterize the latter co-payment repayment scenario as impermissible "netting." Pl. Br. at 7. Plaintiffs are incorrect and merely seek to elevate form over substance. There is no netting, because there is simply no "overcharge" to the consumer. Instead, as Dr. Strombom explained in his Report, while the contract between the consumer and the health plan provided that the consumer would pay $0 for the prescription because an out-of-pocket maximum already had been reached, there is an additional administrative step. Strombom Rep. ¶ 41 n. 57. In essence, because of the limits of computer systems, the health plan required the consumer to give money to the pharmacy that the consumer did not owe, and the health plan later made the consumer whole. The consumer did not pay an "overcharge."

Plaintiffs also misstate the facts. To begin with, Plaintiffs criticize Dr. Strombom for not identifying a specific uninjured consumer. Pl. Br. at 10. But Dr. Strombom had no burden to identify specific names within the category he measured. To the contrary, it is Plaintiffs' burden to show antirust impact with common evidence as to this large category of uninjured consumers identified by Dr. Strombom. *New Motor Vehicles*, 522 F.3d at 28 (vacating certification of class where plaintiffs' model did not "include some means of determining that each member of the class was in fact injured"). In any event, Plaintiffs withheld from their own data the patient-identifier information that would have allowed Dr. Strombom to make that specific connection, which in any event is not necessary to support his estimate. Strombom Rep. ¶ 43 n.58.[5]

Further, Plaintiffs ignore the fact that Dr. Strombom used a widely-credited data set from OptumHealth—which Plaintiffs do not challenge—to undertake the consumer-level analysis that Plaintiffs' incomplete data blocked Dr. Strombom from completing, and this analysis showed there were patients that had ***a $0 payment across all of their transactions***. Strombom Rep. ¶ 42 (estimating [redacted] Ex. 5a (presenting [redacted] It is clear from Dr. Strombom's Report, his Exhibit 5a summarizing his results, and the backup to his analysis that these patients paid $0 ***for each and every transaction***.[6] Contrary to Plaintiffs' claim, there is no "netting" involved. Pl. Br. at 10.

[5] The withheld data also would be necessary for determining which Named Plaintiff health plan members are proper class members, which is the ascertainability inquiry discussed below. *See infra* Section IV.

[6] Plaintiffs refer to Dr. Conti's testimony (Pl. Br. at 10, n.7), but her review was so superficial that she did not even bother to look at the support for Dr. Strombom's calculations. *See* Conti Sept. Dep. 207:10-208:23, attached as Exhibit 2 to the accompanying Declaration of Peter J. Carney in Support of Defendants' Opposition to End-Payor Plaintiffs' Motion to Exclude the Testimony of Dr. Bruce A. Strombom ("Carney Decl."). Further, Dr. Conti admitted that she "didn't exclude people who . . . met out-of-pocket maximum," and in reaching her opinions did not evaluate "how often you might have consumers that met their out-of-pocket maximum or that had satisfied a deductible and, thus, might be excluded from the class." Conti July Dep. 112:14-113:3; 114:10-17, Carney Decl. Ex. 1.

Last, Plaintiffs incorrectly portray Dr. Strombom's estimate of uninjured consumers in this category as being based solely on prescription claims included in Plaintiffs' data. Pl. Br. at 10 n.6. But Plaintiffs ignore the patient-level information included in the OptumHealth data cited by Dr. Strombom. Strombom Rep. ¶ 43 ("Using these shares [from Plaintiffs' incomplete data] and the results from my analysis of the OptumHealth data described above, I estimate that approximately [redacted] consumer class members would be uninjured by the alleged anticompetitive product switching strategy.").

Consumers who used Warner Chilcott coupons were not injured. Plaintiffs assert (at 9-10) a similar "offset" argument regarding Dr. Strombom's estimate of uninjured coupon users. But Plaintiffs ignore that their expert, Dr. Conti, adjusts her own analysis because consumers using coupons in the actual world may be worse off, and thus uninjured, in Plaintiffs' but-for world. Conti Sept. Dep. Tr. 225:2-11 ("I conclude that they wouldn't have been injured on any prescription [when] such a coupon was used."). Adjusting for coupons is consistent with *Nexium*, which considered the effects of consumer coupons as part of the impact analysis. *Nexium*, 777 F.3d at 29 (evaluating whether "with coupons, the actual branded Nexium copayment during class period was lower than the but-for generic copayment would have been").

Further, consistent with *Nexium*, Dr. Strombom's economic analysis starts with data showing more than [redacted] unique consumer coupon users and calculates that there are [redacted] of uninjured consumer coupon users in the class. Strombom Rep. ¶ 53-55. Plaintiffs do not contest his further conclusion that determining a more precise number would require an individualized inquiry. *Id.* ¶ 55. Such inquiry would look into each coupon user's purchases: whether the consumer purchased in some instances without a coupon and if so was injured in those non-coupon transactions; whether the consumer would

have purchased the generic if available; and the consumer's co-pay amount. *Id.* As *Nexium* explains, these are relevant factors for each transaction, i.e., they can change the answer for any specific prescription transaction to the essential question for impact—"whether the but-for price absent foreclosure would have been lower than the actual class period price . . . ." *Nexium*, 777 F.3d at 28. Again, there is no necessary requirement to "net" different transactions in Dr. Strombom's analysis as part of an inquiry into antitrust impact.[7] Id. at 29 (reviewing coupon usage for impact analysis).

* * *

In sum, Dr. Strombom's testimony is admissible and helpful in confirming that Plaintiffs failed to exclude thousands of uninjured consumers. *See, e.g.*, *New Motor Vehicles*, 522 F.3d at 28 (rejecting proposed class that failed to screen out uninjured class members).

B. Dr. Strombom's Showing That Plaintiffs Failed To Exclude A Substantial Number Of TPPs From The Class Is Admissible

Plaintiffs contend that antitrust injury occurs at the moment of an overcharge, and that subsequent offsets and rebates require "netting" and so are not relevant for the antitrust injury inquiry. Pl. Br. at 8. From this, Plaintiffs argue that Dr. Strombom's calculation estimating that some 40% of TPPs were not injured is inadmissible. Plaintiffs' argument rests on the incorrect notion that the offsets are legally irrelevant to the antitrust injury inquiry. Plaintiffs' relevance argument fails for several reasons.

First, Plaintiffs' Motion does not challenge the economic foundation of Dr. Strombom's analysis—"that third party payors may pay the same or more for each prescription in the but-for world." Strombom Rep. ¶ 58. This lack of impact occurs in several instances, including when:

[7] Plaintiffs refer to Dr. Conti's testimony about coupon users but she concededly undertook no consumer level analysis (Conti Sept. Dep. 227:2-13) and no analysis of the propensity of consumers who use coupons to use them for all prescriptions (*id.* at 227:14-18 ("I have no opinion about that.")).

(i) "the difference between the brand price and the but-for world generic price is smaller than the difference in a plan's brand and generic copays"; and (ii) the manufacturer rebates on the brand drive the price for the brand below the cost to the health plan for the generic. *Id*. ¶¶ 58-61.[8] Plaintiffs' Motion thus does not contest that plan-specific factors, "including plan cost-sharing provisions, plan attributes, and the size of the rebates received from the manufacturer determine whether a plan was damaged by the alleged anticompetitive actions, was unharmed, or possibly even benefitted from the alleged delay in generic entry." *Id*. ¶ 58.

Second, Plaintiffs' Motion does not challenge Dr. Strombom's analysis of these plan-specific factors to the extent they relate to his criticism of Dr. Conti's damage model or her damages estimate. Dr. Conti, for example, adjusts her aggregate damages estimation to account for Warner Chilcott rebates that would not be available to TPPs in the but-for world. Conti Opening Rep. ¶ 63, Carney Decl. Ex. 3. Dr. Strombom showed that [redacted] Strombom Rep. ¶ 63 & Ex. 8 ([redacted]). This rebate analysis alone shows the need for an individualized inquiry to asses both impact and damages as to TPPs. *Id*. ¶ 64.

Third, Plaintiffs focus their challenge on Dr. Strombom's showing that health-plan-specific rebate and cost sharing factors would result in a substantial portion of the TPPs paying less on average across all prescriptions in the hypothetical scenario examined. Strombom Rep. ¶¶ 65-66; Pl. Br. at 7. But Plaintiffs' challenge ignores much of Dr. Strombom's work. The

[8] Unlike in *Nexium*, 777 F.3d at 28-29, the record here shows that consumers pay their copays directly to the retail pharmacy. *See* Strombom Rep. ¶¶ 28-30. TPPs are not directly involved in the retail transaction; they do not pay for prescriptions directly and do not bill consumers later for copays. *See infra* Section III.B.

foundation for Dr. Strombom's analysis was his showing that "in many instances" the "adjusted but-for generic price" ***on individual prescriptions paid by named plaintiffs*** was "greater than the actual price paid by Named Plaintiffs." Strombom Rep. ¶ 65. These data support Dr. Strombom's economic opinion, and alone are strong evidence of the need for an individual inquiry as to impact. Plaintiffs' Motion does not challenge this analysis, which does not require "netting" of different prescription transactions.

Additionally, Dr. Strombom took his analysis several steps further. In the hypothetical scenario from Dr. Conti's report that Dr. Strombom used to illustrate his criticisms, he evaluated the Named Plaintiffs' experience across the entire damages period and showed that two of the four suffered no economic injury on Delzicol. That is to say, the weighted average actual Delzicol price per pill for the plan was less than or equal to the estimated weighted average but-for generic price. Strombom Rep. ¶ 65 & Ex. 9(f). *Nexium* confirmed as relevant to antitrust impact this same type of analysis, but there found it insufficient as a ***factual*** matter. *Nexium*, 777 F.3d at 28 ("Defendants argue that [TPP] members were not injured because with the rebates, the actual class period Nexium price was lower than the but-for generic price. However, defendants have not shown that this is the case.").

Dr. Strombom also used the OptumHealth data to show more broadly that net of rebates, [redacted]. Strombom Rep. ¶ 66 & Ex. 11. This is precisely the type of analysis invited by the First Circuit in *Nexium*. There, in response to Defendants' criticism of Plaintiffs' use of averages "to determine fact of injury" for TPPs,[9] the Court stated defendants "cannot simply speculate that a more than de minimis number of class

[9] Like Plaintiffs' expert in *Nexium*, Dr. Conti claims her aggregate damages analysis, which uses aggregate average prices, shows fact of injury. *Nexium*, 777 F.3d at 28 n.24.

members departed from the average" TPP. *Nexium*, 777 F.3d at 28 n.24. Dr. Strombom's analysis provides the support invited by the First Circuit. For the health plans in the OptumHealth data, Dr. Strombom calculated that [redacted] (Strombom Rep. ¶ 66), that is to say, they "departed from the average" TPP. Dr. Strombom's analysis—which shows that Dr. Conti's "use of an aggregate damages method fails to assess whether a significant number of third-party-payor class members were injured by the alleged conduct"—is consistent with *Nexium* and is admissible and helpful.

Contrary to Plaintiffs' suggestion, the situation here is nothing like *Herbert v. Lisle Corp.*, 99 F.3d 1109 (Fed. Cir. 1996), which is not a *Daubert* case. Pl. Br. at 5, n.2. In *Herbert*, the Federal Circuit reversed because the trial court allowed plaintiff's expert in a patent case to make an incorrect statement of law to the jury about the prior art. 99 F.3d at 1117. Here, Dr. Strombom offers no opinions on the law. The limited portion of his third-party-payor analysis challenged by Plaintiffs' Motion is correct as a matter of economics (indeed, Plaintiffs do not contend otherwise), and invited by the First Circuit.

III. NUMEROUS STATES AT ISSUE PERMIT THE PASS-ON DEFENSE, WHICH MAKES DR. STROMBOM'S PASS-ON ANALYSIS RELEVANT

Plaintiffs seek damages under the laws of 26 jurisdictions, not federal law, for alleged overcharges passed on to them. *See* End-Payor Pls.' Consol. Second Am. Class Action Compl. ¶¶ 61-64, ECF No. 124.[10] Many of these jurisdictions provide for a pass-on defense as to

[10] Although federal law limits recovery of damages in antirust cases to direct purchasers, many states allow indirect purchasers to recover under state antitrust law for overcharges allegedly passed-on to them, but only to the extent they actually suffered damages and did not in turn pass-on the alleged overcharge. *See, e.g., Kellogg Co. v. F. Hoffman La Roche Ltd. (In re Vitamins Antitrust Litig.)*, 259 F. Supp. 2d 1, 2, 8-9 (D.D.C. 2003) (discussing *Hanover Shoe*, *Illinois Brick*, and state repealer statutes and finding

indirect purchasers, like the Plaintiffs here, to protect against duplicative recoveries. Dr. Strombom opines based on substantial economic analysis that TPPs such as Plaintiffs passed on any alleged overcharge and were uninjured. Strombom Rep. ¶ 72. The pass-on occurs through premiums (or in the case of union health plans like Named Plaintiffs, employer contributions) charged by the third-party health plan for insurance. *Id.* ¶¶ 67-68.[11] Because they pass on any alleged overcharge, pursuant to many of the state laws at issue, third-party-payor members of the class have no damages to recover. Strombom Rep. ¶ 72.

A. The Pass-On Defense Applies Here To Protect Defendants From The Risk of Duplicative Recovery

Plaintiffs incorrectly claim that "most" of the class states "preclud[e] the 'pass-through' defense in all circumstances." Pl. Br. at 12-13. While in fact most class states permit a pass-on defense in order to protect defendants from duplicative recovery, it is enough here that Plaintiffs concede that at least four states provide for a pass-on defense—Nebraska, New Mexico, Arizona, and Wisconsin.[12] Additionally, Plaintiffs also ignore the express availability of the pass-on defense in ten additional class states.[13] Dr. Strombom's testimony regarding pass-on is therefore

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determination of "actual damages" to necessarily involve consideration of the pass on of alleged overcharges).

[11] Dr. Strombom confirmed his pass-on opinion with empirical analysis of multiple data sets. Each analysis showed a direct, strong, and statistically significant correlation–up to 99.9% based on one data set–between health care costs, including the cost of prescription drugs, incurred by insurers and the premiums that they charged. Strombom Dep. 186:21-187:11; Strombom Rep. ¶¶ 67-72 & Exs. 12-14.

[12] *See* Pl. Br. at 12, 13 n.11; *see also, e.g.*, Neb. Rev. Stat. § 59-821.01 (allowing a pass-on defense "so as to avoid duplication of recovery of such damages"); *Olstad v. Microsoft Corp.*, 700 N.W.2d 139, 158 (Wisc. 2005) ("Duplicative prosecution is one thing; duplicative recovery is another.").

[13] Florida, Maine, Michigan, Minnesota Nevada, New York, North Dakota, Rhode Island, South Dakota, West Virginia, and the District of Columbia also allow consideration of the pass-on defense. *See, e.g.*, **Florida**: *In re TFT-LCD (Flat Panel) Antitrust Litig.*, MDL. No. 1827, 2013 U.S. Dist. LEXIS 16864, *53-54 (N.D. Cal. Feb. 6, 2013) (denying plaintiffs' motion for judgment on the pleadings and explaining "[t]here is no clear Florida case law precluding the pass-on defense under the FDUTPA"); **North Dakota**: N.D. Cent. Code § 51-08.1.08(4) ("In any action for damages under this section, any defendant, as a partial or complete defense against a claim for damages, is entitled to prove that the plaintiff purchaser, or seller in the chain of manufacture, production, or distribution, who paid any overcharge or received any

relevant and helpful.

B. Plaintiffs' Claims Are Subject To The Pass-On Defense: There Is No Physical Chain Of Distribution Limitation On The Pass-On Defense

Having conceded that the pass-on defense is available under state laws here, Plaintiffs fall back on an unsupported assertion that some states restrict the defense to resellers in the "chain of distribution." Pl. Br. at 13-14. But the cases they cite do not so hold and the overcharges here relate to payments, not product distribution. The proper focus thus is on the flow of funds.

Courts have found health plans like Named Plaintiffs to be part of the pharmaceutical supply and payment chain because they act as financial intermediaries, passing on any alleged "overcharges" through premiums. *See, e.g.*, *Ironworkers Local Union v. AstraZeneca Pharm.*, 634 F.3d 1352, 1364-65 & n.26, 1369 (11th Cir. 2011) (RICO claim dismissed because insurer did not "plausibly suffer[] economic injury" and explaining that insurer can "adjust its charged premium rate" charged to its members when its costs increase); *Int'l Bd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 824 (7th Cir. 1999) (Health plans "are just financial intermediaries. They collect the premiums and spend them to provide the contracted-for care; their books balance whether the costs of care are high or low.").

Plaintiffs provide no legal support for their chain of distribution limitation. They cite no case in which a court rejected a pass-on defense applying such a limitation.[14] Plaintiffs' reliance

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underpayment passed on all or any part of the overcharge or underpayment to another purchaser or seller in that action."); **Minnesota**: *In re TFT-LCD (Flat Panel) Antitrust Litig.*, MDL. No. 1827, 2012 U.S. Dist. LEXIS 182373, at *60-61 (N.D. Cal. Dec. 26, 2012) ("allowing a pass-on defense is consistent with the Minnesota Antitrust Act because plaintiffs will recover their 'actual damages sustained'"); **Maine**: *McKinnon v. Honeywell Int'l, Inc.*, 977 A.2d 420, 427 (Me. 2009) (requiring indirect purchaser under Maine law to show that it paid higher prices and that such overcharge was not absorbed upstream); **Michigan**: *In re Vitamins Antitrust Litig.*, 259 F. Supp. 2d 1, 9 (D.D.C. 2003) (pass through defense available under Michigan's antitrust law).

[14] Plaintiffs' federal antitrust cases (Pl. Br. at 13) are inapposite. Those cases address a physical chain of distribution and resale simply because that was the fact pattern presented in each case. The actual holding

on *Blue Cross & Blue Shield United v. Marshfield Clinic* is misplaced because that case did not even address the pass-on defense. 65 F.3d 1406, 1414 (7th Cir. 1995) (addressing standing of insurer to sue where insurer did not have a separate contract with the Plaintiff).

In fact, if there were a chain of distribution limitation, insurers and health plans like Named Plaintiffs would lack standing. Under Plaintiffs' theory, the last physical reseller of a prescription drug in the chain of distribution is the retail pharmacy. But retail pharmacies typically "sell" prescription drugs not to health plans, but to patients and pharmacy benefit manager ("PBMs"), who each pay a portion of the drug's retail pharmacy cost. [redacted].[15] One of the nation's largest PBMs made the same point explicitly in its 10-K: "We, not our clients, are obligated to pay the retail pharmacies in our networks the contractually agreed upon amount for the prescription dispensed, as specified within our provider contracts."[16] Thus, under their own theory, Plaintiffs would lack standing

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in each case, however, pertains to the pedestrian rule that indirect purchasers do not have standing to sue for damages under federal antitrust law. *E.g.*, *Ill. Brick Co. v. Ill.*, 431 U.S. 720, 730, 746 (1977) (restricting federal antitrust claims to direct purchasers because the Court was "unwilling to open the door to duplicative recoveries"); *Paper Sys. v. Nippon Paper Indus. Co.*, 281 F.3d 629, 632–33 (7th Cir. 2002) (stating that *Illinois Brick* and *Hanover Shoe* "concentrate damages in the hands of the initial purchasers" and "prevent double recoveries"); *In re Brand Name Prescription Drugs Antitrust Litig.*, MDL No. 94-897, 1996 U.S. Dist. LEXIS 4335, at *92-95 (D. Ill. Apr. 4, 1996) (unless "the intermediate is under the control of the antitrust defendant," *Illinois Brick* applies to avoid multiple recovery). Plaintiffs' citations for a small fraction of the class states (Pl. Br. at 13, n.11) do not create a chain of distribution limitation but instead emphasize avoiding duplicative recovery. *Bunkers' Glass Co. v. Pilkington PLC*, 206 Ariz. 9 (Ariz. 2003) (no discussion of a chain of distribution requirement in holding that Arizona allows indirect purchaser actions); N.M. Stat. Ann. § 57-1-3 (allowing pass-on defense "in order to avoid duplicative liability"); Neb. Rev. Stat. § 59-821.01(1) (allowing pass-on defense "so as to avoid duplication of recovery of such damages").

[15] *E.g.*, EPP WISCMASONS 000204, at 211 [redacted]

[16] *See* Express Scripts, Form 10-K for the fiscal year ended December 31, 2013, p. 63, https://www.sec.gov/Archives/edgar/data/1532063/000119312513063930/d450292d10k.htm; *see also* Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," at 4 (August 2005), https://www.ftc.gov/sites/default/files/ documents/reports/pharmacy-benefit-managers-ownership-mail-

because they do not purchase pharmaceuticals; instead, they reimburse PBMs for purchases.

Last, Plaintiffs' superficial footnote (Pl. Br. at 14 n.12) does not seriously challenge the substance of Dr. Strombom's opinion. Plaintiffs focus on the absence of an "increase" in premium costs to cover the alleged overcharge, but they ignore that Plaintiffs themselves allege they were overcharged because they were not able to purchase lower cost generic drugs. As Dr. Strombom explained, the cost of Defendants' branded products were part of the premium setting process, and passed on through such premiums. Strombom Dep. 187:12-188:7. Plaintiffs' further suggestion that drug costs are not relevant because premiums cover health care costs "generally" ignores Dr. Strombom's testimony that all drugs costs are factored into the premiums set for health plans; no drug costs are ignored. *Id.* at 258:19-59:2. In fact, Named Plaintiffs have admitted to passing on increases in pharmaceutical costs to their members. *E.g.*, Strombom Rep. ¶¶ 67-68; Defs.' Opp'n to Mot. for Class Cert. at 9, n.3, ECF. No. 397 ("Class Cert. Opp'n").

IV. DR. STROMBOM'S OPINION THAT PLAINTIFFS PROVIDE NO METHOD FOR ASCERTAINING CLASS MEMBERSHIP IS ADMISSIBLE

Plaintiffs misstate Dr. Strombom's opinion regarding ascertainability. Dr. Strombom does not offer an opinion that Dr. Conti should have identified each class member. *See* Pl. Br. at 15. Rather, Dr. Strombom opined that Dr. Conti provided no method—let alone one with "objective criteria that would be administratively feasible to implement"—for determining whether potential class members were in our out of the class. Strombom Rep. ¶ 14; *see also id.* ¶¶ 35, 39, 41, 47, 96-98.

Specifically, Dr. Strombom explains that Dr. Conti's aggregated methodology focused on prescriptions and thus provides no way to identify potential class members who are: (i) excluded

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order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf (explaining retail pharmacies "receive revenue" from consumers and PBMs "for filling PBM administered prescriptions").

by the class definition, such as persons or entities that fail the dual-purchase requirement, consumers with flat copays, or consumers who purchased Asacol HD prior to March 8, 2013; or (ii) excluded from the class because they were uninjured, such as brand loyal consumers, consumers who paid $0 for their prescriptions, and consumers who would have switched to a generic but with no cost savings. *E.g.*, *id*. ¶¶ 14, 39, 94-95; Strombom Dep. Tr. 271:22-272:9; 273:5-24. In fact, Dr. Conti concedes that her methodology does not provide a feasible method using objective criteria for identifying class members. *See* Conti July Dep. Tr. 160:22-161:6.

Plaintiffs misread the law in claiming that Dr. Strombom's opinions on lack of ascertainability are inconsistent with First Circuit precedent. Plaintiffs only cite *Matamoros v. Starbucks Corp.*, 699 F.3d 129 (1st Cir. 2012). Pl. Br. at 15. But Dr. Strombom's analysis is wholly consistent with *Matamoros* in that he shows why, using Plaintiffs' approach, this Court would not be able to meet its obligation "to resolve the question of whether class members are included or excluded from the class by reference to objective criteria." *Matamoros*, 699 F.3d at 139 (citation and quotation marks omitted); *see, e.g.*, Strombom Rep. ¶ 14; Class Cert. Opp'n at 5. In the First Circuit, there needs to be a "demonstrable correspondence between the class definition and the requirements of proffered evidence to enable [the court] ***to determine whether a particular individual belongs in the class***." *Kent v. SunAmerica Life Ins. Co.*, 190 F.R.D. 271, 278 (D. Mass. 2000) (emphasis added).[17] Dr. Strombom details why nothing from Dr. Conti, or otherwise proposed by Plaintiffs, will help the Court meet this obligation. Strombom Rep. ¶¶ 35, 39, 41, 44, 47, 57, 89-90, 96-98.

[17] Courts have rejected Plaintiffs' argument that the class definition is sufficient. *See, e.g., In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 569 (E.D. Tenn. 2014) (rejecting argument that class definition provided the objective criteria to determine class membership and finding that the class was not ascertainable because plaintiffs' expert did not provide a method for identifying class membership using objective criteria).

A court must know that "it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members." *Nexium*, 777 F.3d at 19 (same); *Local 589, Amalgamated Transit Union v. Mass. Bay Transp. Auth.*, No. 13-cv-11455-ADB, 2016 U.S. Dist. LEXIS 128100, at *7, 14 (D. Mass. Sept. 20, 2016) (Burroughs, J.) (denying class certification and stating court must be able to determine whether a particular individual is a member of a class). The mechanism must be "administratively feasible" and "protective of defendants' Seventh Amendment and due process rights" for the court to proceed with certification. *Nexium*, 777 F.3d at 19 (citations and quotation marks omitted); *Carrera v. Bayer Corp.*, 727 F.3d 300, 311 (3d Cir. 2013) (denying class certification where plaintiffs "suggested no way to determine the reliability" of their proposed model to identify class members). For multiple categories, Dr. Strombom has shown that Plaintiffs have provided no objective criteria for establishing class membership and no administratively feasible mechanism for distinguishing injured from uninjured class members. Strombom Rep. ¶¶ 35, 39, 41, 44, 47, 57, 89-90, 96-98. Further, he has shown that a burdensome, individualized inquiry would be required to identify class members. *Id.* ¶¶ 33-74. Dr. Strombom's work is directly consistent with First Circuit law and admissible and helpful under *Daubert* and Federal Rule of Evidence 702.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that under-seal copies of this opposition and accompanying papers will be e-mailed to End-Payor counsel of record on October 10, 2017, and a redacted public version will be filed on ECF and electronically sent to the registered participants as identified on the Notice of Electronic Filing (NEF) pursuant to the Case Management Order.

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